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DOCKET NO.: CELL-0294/PA519-USW01
PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

David Paul Humphreys, et al.

Application No.: 10/531,402 Group Art Unit: Not Yet Assigned

Filing Date: October 11, 2005 Examiner: Not Yet Assigned

For: E.COLI HOST CELLS WITH MODIFIED PHOS/PSTS PERIPLASMIC

PHOSPHATE-BINDING PROTEINS, AND METHOD OF

MANUFACTURING RECOMBINANT FABS

DATE OF DEPOSIT: Lecember 5,

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA,

TYPED NAME: Elizabeth A. McLoud

Confirmation No.: 8981

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

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application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required. П In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore: Certification in Accordance with § 1.97(e) is attached; or The fee of \$180.00 as set forth in § 1.17(p) is attached. П In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in \$1.17(p). Copies of reference numbers 1 - 31 and 35-40 listed on the attached Form PTO-1449 are enclosed herewith. Copies of reference numbers 32 - 34 on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i). Copies of references are not being submitted because they were previously cited by or submitted to the U.S. Patent and

Trademark Office in patent application number

, filed

for

which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

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Form PTO-1449 Modified

List of Patent and Publications Cited by Applicant (Use several sheets if necessary)

U.S. Department of Commerce Patent and Trademark Office

Docket No. CELL-0294/ PA519-USw01	Application No. 10/531,402
Applicant David Paul Humphreys,	et al.
Filing Date October 11, 2005	Group Not Yet Assigned
Confirmation No. 8981	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	1	Amemura, M., et al., "Cloning of and complementation tests with alkaline			
		phosphatase regulatory genes (phoS and phoT) of Escherichia coli," J. of			
	<u> </u>	Bacteriology, 1982, 152(2), 692-701			
	2	Blattner, F.R., et al., "The complete genome sequence of Escherichia coli K-12," <i>Science</i> , 1997 , 277, 1453-1462			
	3	Blomfield, I.C., et al., "Allelic exchange in Escherichia coli using the Bacillus			
		subtilis sacB gene and a temperature-sensitive pSC101 replicon," Molecular			
		Microbiology, 1991, 5(6), 1447-1457			
	4	Carrier, A., et al., "recombinant antibody-alkaline phosphatase conjugates for			
	ļ	diagnosis of human IgGs: application to anti-HBsAg detection," J. of Immunological			
		Methods, 1995, 181, 177-186			
	5	Collins-Racie, L.A., et al., "Production of recombinant bovine enterokinase catalytic			
		subunit in Escherichia coli using the novel secretory fusion partner DsbA,"			
		Bio/Technology, 1995 , 13, 982-987			
	6	Cunningham, B.C., et al., "High-resolution epitope mapping of hGH-Receptor			
		interations by alanine-scanning mutagenesis," Science, 1989, 244, 1081-1085			
	7	Dalbøge, H., et al., "A novel enzymatic method for production of authentic hGH			
		from an Escherichia coli produced hGH-precursor," Bio/Technology, 1987, 5, 161-			
		164			
	8	di Guan, C., et al., "Vectors that facilitate the expression and purification of foreign			
		peptides in Escherichia coli, by fusion to maltose-binding protein," Gene, 1988, 67,			
		21-30			
	9	Egmond, M.R., et al., "Engineering surface charges in a subtilisin," in Subtilisin			
		Enzymes: Practical protein Engineering, Bott, R., et al.(Eds.), 1996, 219-228			
	10	Gräslund, T., et al., "Strategy for highly selective ion-exchange capture using a			
		charge-polarizing fusion partner," J. of Chromatography A, 2002, 942, 157-166			
EXAMINER		DATE CONSIDERED			





Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. CELL-0294/ PA519-USw01 Applicant David Paul Humphreys, Filing Date October 11, 2005 Confirmation No. 8981	Application No. 10/531,402 et al. Group Not Yet Assigned		
ОТНЕ	R DOCUMENTS (Includ	ling Author, Title, Date,	Pertinent Pages, Etc.)		
11	1		ein domain to allow efficient ion-		
12	exchange recovery," <i>Protein Engineering</i> , 2000 , <i>13(10)</i> , 703-709 Hamilton, C.M., et al., "New method for generating deletions and gene replacements in <i>Escherichia coli</i> ," <i>J. of Bacteriology</i> , 1989 , <i>171(9)</i> , 4617-4622				
13	Humphreys, D.P., et al., "Therapeutic antibody production technologies: molecules, applications, expression and purification," Current Opinion in Drug Discovery and Development, 2001, 4(2), 172-185				
14	Jonasson, P., et al., "Genetic design for facilitated production and recovery of recombinant proteins in <i>Escherichia coli</i> ," <i>Biotechnology & Applied Biochemistry</i> , <i>England</i> , 2002 , <i>35</i> , 91-105				
15	Link, A.J., et al., "Methods for generating precise deletions and insertions in the genome of wild-type <i>Escherichia coli</i> : application to open reading frame characterization," <i>J. of Bacteriology</i> , 1997 , <i>179(20)</i> , 6228-6237				
16	Luecke, H., et al., "High specificity of a phosphate transport protein determined by hydrogen bonds," <i>Nature</i> , 1990 , <i>347</i> , 402-406				
17	Marttila, A.T., et al., "Engineering of chicken avidin: a progressive series of reduced charge mutants," <i>FEBS Letts.</i> , 1998 , <i>441</i> , 313-317				
18	Meyer, D.E., et al., "Purification of recombinant proteins by fusion with thermally-responsive polypeptides," <i>Nature Biotechnology</i> , 1999 , <i>17</i> , 1112-1115				
19					
20	Niederauer, M.Q., et al., "Characterization and polyelectrolyte of β - galactosidase containing genetic fusions of charged polypeptides," <i>Biotechnology Progress</i> , 1994 , 10, 237-245				
EXAMINER	AMINER DATE CONSIDERED				



List of Paten Cited b (Use several s	-1449 Modified t and Publications by Applicant sheets if necessary) nent of Commerce Trademark Office	Docket No. CELL-0294/ PA519-USw01 Applicant David Paul Humphreys, Filing Date October 11, 2005 Confirmation No. 8981	Application No. 10/531,402 et al. Group Not Yet Assigned	
ОТНЕ	R DOCUMENTS (Includ	ling Author, Title, Date,	Pertinent Pages, Etc.)	
21			lase: the generation, purification	
		in," J. of Immunological N		
22	O'Brien, P.M., et al., "Bacterial expression and purification of recombinant," Protein			
	Expression & Purification, 2002, 24, 43-50			
23	Ong, E., et al., "Enzyme immobilization using the cellulose-binding domain of a			
24	Cellulomonas Fimi exoglucanase," Bio/Technology, 1989, 7, 604-607 Persson, M., et al., "Enzyme purification by genetically attached polycysteine and			
	polyphenylalanine affinity tails," <i>Analytical Biochemistry</i> , 1988 , <i>172</i> , 330-337			
25	Plückthun, A., et al., "New protein engineering approaches tomultivalent and			
	bispecific antibody fragments," <i>Immunotechnology</i> , 1997 , 3, 83-105			
26	Sassenfeld, H.M., et al., "A polypeptide fusion designed for the purification of			
	recombinant proteins," Bio/technology, 1984, 2, 76-81			
27	Sassenfeld, H.M., "Engineering proteins for purification," <i>Tibtech</i> , 1990, 8, 88-93			
28	Smith, D.B., et al., "Single-step purification of polypeptides expressed in Escherichia			
	coli as fusions with glutathione S-transferase," Gene, 1988, 67, 31-40			
29	Stempfer, G., et al., "Improved refolding of an immobilized fusion protein," Nature			
	Biotechnology, 1996, 14, 329-334			
30	Verma, R., et al., "Antibody engineering: comparison of bacterial, yeast, insect and			
	mammalian expression system," J. of Immunological Methods, 1998, 216, 165-181			
EXAMINER	XAMINER DATE CONSIDERED			



	100	TRADE			
Form PTO-1449 Modified			Docket No CELL-029 PA519-US	94/	Application No. 10/531,402
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant David Paul Humphreys, et al.			
U.S. Department of Commerce Patent and Trademark Office		Filing Dat October 1		Group Not Yet Assigned	
			Confirmat 8981	ion No.	
O 7.	THE	R DOCUMENTS (Includ	ling Author	, Title, Date, F	Pertinent Pages, Etc.)
	31		general pro-	cedure for the p	genesis using M13-derived production of point mutations in $O(20)$, 6487-6500
EXAMINER				DATE CONS	SIDERED





Form PTO-1449 Modified				Docket No. CELL-0294/ PA519-USw01	Application No. 10/531,402		
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)			Applicant David Paul Humphreys, et al.				
U.S. Department of Commerce Patent and Trademark Office			Filing Date October 11, 2005	Group Not Yet Assigned			
			Confirmation No. 8981				
		U. S	S. PATENT	T DOCUMENTS			
Examiner Initial		Document No.	Date	Name		Class	Subclass
	32	4,532,207	07/30/85	Brewer, et al.		435	68
	33	5,304,472	04/19/94	Bass, et al.		435	69.1
	34	5,783,423	07/21/98	Wood, et al.		435	69.6
		FORE	IGN PATE	ENT DOCUMENTS		_	
Examiner Initial		Document No.	Date	Country		Translation YES NO	
Initial	35	WO 98/18946 A1	05/07/98	PCT		IES	110
	36	WO 00/61725 A1	10/19/00	PCT			
	37	WO 2004/031188 A1	04/15/04	PCT			
	38	WO 2004/035792 A1	04/29/04	PCT			
	39	737 747 A2	10/16/96	EP		X abstract	
	40	224,082	11/06/24	GB			
EXAMINER			DATE CONSIDE	RED			